

§ 890.1925

(b) *Classification*. Class II (performance standards).

§ 890.1925 Isokinetic testing and evaluation system.

(a) *Identification*. An isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59230, Nov. 3, 1998]

Subpart C [Reserved]

Subpart D—Physical Medicine Prosthetic Devices

§ 890.3025 Prosthetic and orthotic accessory.

(a) *Identification*. A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3075 Cane.

(a) *Identification*. A cane is a device intended for medical purposes that is used to provide minimal weight sup-

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port while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]

§ 890.3100 Mechanical chair.

(a) *Identification*. A mechanical chair is a manually operated device intended for medical purposes that is used to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include the following: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38816, July 25, 2001]

§ 890.3110 Electric positioning chair.

(a) *Identification*. An electric positioning chair is a device with a motorized positioning control that is intended for medical purposes and that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions.

(b) *Classification*. Class II (performance standards).